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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,604	01/31/2002	Michael Alan Reeve	PA-9912	8189

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AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,604	REEVE ET AL.	
	Examiner	Art Unit	
	Shar Hashemi	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 January 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-11,14-18,21-25 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-11,14-18,21-25 and 27-30 is/are rejected.
- 7) Claim(s) 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 October 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input checked="" type="checkbox"/> Other: "Notice to Comply..." . |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The First and Second Preliminary Amendments (filed 31 January 2002) were received and entered. Claims 3, 12, 13, 19, 20, and 26 were cancelled by amendment. The claims pending in this application are **Claim(s) 1, 2, 4-11, 14-18, 21-25, and 27-30.**

Sequence Rules

2. This application does NOT comply with the sequence rules even though the sequences have been entered by the Scientific and Technical Information Center (see attached "Notice to Comply").

Priority

3. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless

the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

5. Figure 1 is objected to under 37 CFR 1.83(a) because it fails to show the hybridization patterns. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

6. This application contains sequence disclosures (page 109, lines 11-25; page 110, lines 1-35; page 115, lines 10-13; page 121, lines 10-25; page 122, lines 1-23; page 123, lines 5-6; page 129, lines 13-25; page 130, lines 1-15; page 138, lines 10-32; page 139, lines 6-7; page 141, lines 6-7) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Furthermore, sequence disclosures must have SEQ ID NO “identifiers”.

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION IN WHICH COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 – 1.825.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response. The application is not in compliance for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report.

7. The use of the trademark "MetaPhor" (page 119, line 12) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

8. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are *suggested* for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

9. Claim 16 is objected to because of the following informalities: "selected from" should be replaced with Markush type language (i.e. selected from the group consisting of...). Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 2, 4-11, 15 and 29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- A) The terms “affected DNA” and “unaffected DNA” render claims 1, 2, 4-11, and 29 indefinite. It is unclear as to which criteria is utilized to determine which DNA is “affected” or “unaffected.” Amending the claim to define the terms “affected DNA” and “unaffected DNA” would obviate the rejection.
- B) Claim 15 recites a formula comprising the limitations “n!” and “r!” . There is insufficient antecedent basis for this limitation in the claim. Amending the claim to define the limitations “n!” and “r!” .
- C) The phrase “comprises steps a), b) and c) one or more time” renders claim 29 indefinite. It is unclear as to which active step is being employed in the claim 29. Amending the claim to insert an active step (e.g. performing) would obviate the rejection.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 2, 4-11, 14-16, 23-25, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner, Jr. (US 6,329,147 B1 December 11, 2001).

Wagner teaches both a method of making a set of arrays of DNA of interest and a method of providing a mixture of DNA fragments enriched in fragments that are characteristic of a phenotype of interest, which method includes providing affected DNA in

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fragmented form and providing unaffected DNA in fragmented form comprising the limitations set forth in claims 1, 2, 4-11, 14-16, 23-25, and 29 (see whole document, especially col. 2, lines 18-25; col. 3, lines 15-65; col. 4, lines 1-67; col. 6, lines 60-67; col. 7, lines 1-55; col. 8, lines 1-67; col. 10, lines 10-65; col. 14, lines 15-67; col. 21, lines 15-30; col. 24, lines 21-67; col. 29, lines 5-67; col. 37, lines 25-67).

14. Claims 1, 2, 4-11, 14-16, 23-25, and 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Dong et al (US 2002/0142314 A1 October 03, 2002).

Dong et al disclose a double-stranded DNA molecule, a method of making a set of arrays of fragments of DNA of interest, and a method of providing a mixture of DNA fragments enriched in fragments that are characteristic of a phenotype of interest, which method includes providing affected DNA in fragmented form and providing unaffected DNA in fragmented form comprising the limitations set forth in claims 1, 2, 4-11, 14-16, 23-25, and 27-30 (see whole document, especially page 2, par. 37; page 3, par. 50; page 4, par. 56-59; page 5, par. 64-67; page 8, par. 84-88; page 9, par. 90-99; page 10, par. 110-113; page 11, par. 130-131; page 12, par. 131-135).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 17, 18, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al (US 2002/0142314 A1 October 03, 2002).

The teachings and suggestions of Dong et al have been described previously.

Except for *EcoRI*, Dong et al not the six-cutter restriction endonucleases recited in claims 21 and 22.

One of ordinary skill at the time the invention was made would have been motivated to apply any six cutter restriction endonuclease to generate desired DNA fragments to Dong et al disclose a double-stranded DNA molecule, a method of making a set of arrays of fragments of DNA of interest, and a method of providing a mixture of DNA fragments enriched in fragments that are characteristic of a phenotype of interest because six-cutter restriction endonucleases are readily available to yield average pieces of 4,096 bases long. It would have been prima facie obvious to apply any six cutter restriction endonuclease to generate desired DNA fragments to Dong et al disclose a double-stranded DNA molecule, a method of making a set of arrays of fragments of DNA of interest, and a method of providing a mixture of DNA fragments enriched in fragments that are characteristic of a phenotype of interest because six-cutter restriction endonucleases are readily available to yield average pieces of 4,096 bases long.

Thus, an ordinary practitioner would have recognized that the results optimizable variables of number of sets of restriction endonuclease, number of subsets of restriction enzymes, and specific types of six-cutter enzymes could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

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ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific times for amplification was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

CONCLUSION

17. Claims **1, 2, 4-11, 14-18, 21-25, and 27-30** are rejected to and claim 16 is objected to for the reasons set forth above.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840. The examiner can normally be reached Monday-Friday from 8:00AM – 5:00PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

The fax number for this examiner is (703) 746-9038. Before faxing any papers, please inform the examiner to avoid lost papers. Please note the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, Tracey Johnson, whose telephone number is (703) 305-2982.

Examiner Hashemi



Ethan Whisenant, Ph.D.
Primary Examiner
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